Press Release

For media and investors only

Issued: 9 March 2025, London UK

ViiV Healthcare continues to deliver long-acting injectable HIV innovation with late-breaking data and real-world insights across pipeline and portfolio at CROI 2025

- ***Real-world and implementation data highlight effectiveness of Cabenuva (cabotegravir + rilpivirine LA) and Apretude (cabotegravir LA (CAB LA) for PrEP), the only approved long-acting injectable therapies for HIV treatment and prevention, among broad range of communities***
- ***Late-breaking phase IIb data demonstrate the potential of an investigational new long-acting broadly neutralising antibody (bNAb)/CAB LA combination treatment***
- ***Two proof-of-concept studies on an investigational third-generation integrase strand transfer inhibitor (INSTI) and a capsid inhibitor highlight the opportunity for further research into these assets as long-acting antiretrovirals***

London, [9 MARCH 2025] – ViiV Healthcare, the global specialist HIV company majority owned by GSK, with Pfizer and Shionogi as shareholders, today announced the presentation of abstracts from its innovative HIV treatment and prevention portfolio and research pipeline at the Conference on Retroviruses and Opportunistic Infections (CROI 2025).

Kimberly Smith, M.D., MPH, Head of Research & Development at ViiV Healthcare, said: "Our long-acting injectable portfolio is being showcased at CROI 2025 with data on real-world outcomes, demonstrating the impact our industry-leading portfolio is having today. We're also sharing early data from our transformative pipeline, including results from our third-generation integrase inhibitor and partner assets. These assets have the potential to increase dosing intervals beyond what's currently available, aiming to deliver what the community of people living with HIV tells us they want and need."

Key data to be presented at CROI 2025 by ViiV Healthcare and its study partners include:

Portfolio

- **New data assessing *Apretude* (CAB LA for PrEP) in HIV prevention:** Latest data from the PILLAR implementation study, which is assessing strategies for delivering CAB LA at 17 sites in the US, will be presented; clinical assessments will include HIV incidence, HIV diagnostic testing, persistence, and safety and tolerability of CAB LA over 12 months[1]. Findings from the ImPrEP CAB Brazil implementation study will include PrEP coverage and HIV incidence among young, key populations who were given the choice of CAB LA or oral PrEP[2].
- **Long-term real-world and clinical trial data in diverse populations on *Cabenuva* (cabotegravir + rilpivirine long-acting (CAB+RPV LA)):** New data on the utilisation and effectiveness of CAB+RPV LA in people living with HIV in the US will be presented from the Trio Health study[3]. Long-term follow-up data from the real-world OPERA study will include CAB+RPV LA effectiveness in individuals through two years[4], as well as clinical outcomes in women receiving CAB+RPV LA[5]. Long-term data on the efficacy, safety and tolerability of CAB+RPV LA in people living with HIV in sub-Saharan Africa will be presented from the CARES study[6].
- **PASO-DOBLE week 48 subgroup analysis:** New data from the largest head-to-head randomised clinical trial of DTG/3TC vs BIC/FTC/TAF, looked at efficacy and clinically meaningful weight

changes (>5% from baseline) across different subgroups, including but not limited to sex at birth, age groups, ethnicity and prior antiretroviral therapy[7].

Pipeline

- **Late breaking data for a new therapeutic option:** A new phase IIb study with VH3810109 (VH109), an investigational, broadly neutralising antibody (bNAb) offers efficacy and safety findings of the bNAb (subcutaneous and IV administration) in combination with CAB LA[8].
- **New findings from our next generation of INSTIs:** A proof-of-concept clinical study with VH4524184 (VH184), an investigational third-generation integrase inhibitor with potential for long-acting dosing, assessed the drug's exposure-response relationship to HIV-1 at multiple doses and shows findings that support further development[9].
- **Proof of concept data of a partner asset to INSTIs:** A proof-of-concept clinical trial provides insights into the antiviral effects, pharmacokinetics, safety, and tolerability of VH4011499 (VH499), a new, highly potent investigational capsid inhibitor and one of several partner asset options being evaluated for development into long-acting treatment HIV regimens[10].

ViiV Healthcare-sponsored or supported studies to be presented at CROI 2025:

Title	Presenting author	Presentation
Cabotegravir for Pre-exposure prophylaxis (PrEP)		
PILLAR month 12 clinical results: zero HIV acquisition and high persistence with CAB LA for PrEP	T. Khan	Oral Abstract 196 12 March 2025 10:00 AM PT
Performance of HIV RNA screening in the context of long-acting injectable cabotegravir in HPTN 084	S. Delany-Moretlwe	Oral Abstract 195 12 March 2025 10:00 AM PT
ImPrEP CAB Brasil: Enhancing PrEP Coverage with CAB-LA in Young Key Populations	B. Grinsztejn	Oral Abstract 192 12 March 2025 10:00 AM PT
Estimation of prevention-effective CAB-LA concentrations among MSM/TGW in HPTN 083	B. Hanscom	Oral Abstract 193 12 March 2025 10:00 AM PT
Response to HIV Treatment After Long-Acting Cabotegravir Pre-exposure Prophylaxis in HPTN 083	R. Landovitz	Oral Abstract 197 12 March 2025 10:00 AM PT
No increased risk for hypertension with CAB-LA compared to TDF/FTC for PrEP: results from HPTN 084	S. Delany-Moretlwe	Poster 820
High incidence of curable sexually transmitted infections in HPTN 084: a tertiary analysis	H. Nuwagaba-Biribonwoha	Poster 1226
PrEP choices among sexual and gender minorities in Brazil: the ImPrEP CAB-LA study	B. Grinsztejn	Poster 1356
Depression and suicide risk among sexual and gender minorities: insights from the ImPrEP CAB Brazil	D. Richer Araujo Coelho	Poster 1302
Patterns of first choice, switching, and discontinuation of oral and injectable PrEP among adolescents from sexual and gender minorities in Brazil	L. Magno Santos de Sousa	Poster 1203
Acceptability of long-acting cabotegravir among pregnant and lactating people in South Africa	N. Wara	Poster 1357

Impact of rapid long-acting prep scale-up among MSM: closing the unmet needs and towards ending HIV	H. Wang	Poster 1297
Expanding the PrEP method market: Early insights from offering oral PrEP, PrEP ring, and injectable CAB PrEP for HIV prevention across five countries in Africa	N. Naidoo	Poster 1354
Dynamic choice HIV prevention in the context of injectable cabotegravir (CAB-LA): a model-based cost-effectiveness analysis	M. Hickey	Poster 1293
Use of DNA profiling to resolve discrepant HIV tests in the setting of injectable cabotegravir PrEP	J. Fogel	Poster 1193
Cabotegravir for Treatment		
Randomized trial of cabotegravir and rilpivirine long-acting in Africa (CARES): week 96 results	C. Kityo	Oral Abstract 202 12 March 2025 12:15 PM PT
Proof-of-concept trial of oral VH4011499 (VH-499), a new HIV-1 capsid inhibitor	P.l Benn	Oral Abstract 153 11 March 2025 10:21-10:30 PT
VH3810109 (N6LS) efficacy and safety in adults who are virologically suppressed: The EMBRACE study	B. Taiwo	Oral Abstract 203 12 March 2025 12:39-12:46 PT
Long-term CAB+RPV LA effectiveness in virologically suppressed individuals in the OPERA cohort	M. Sension	Poster 674
Clinical outcomes among virologically suppressed women receiving CAB+RPV LA in the OPERA cohort	J. Altamirano	Poster 676
Outcomes on cabotegravir + rilpivirine in suppressed people with HIV (PWH) in TRIO health US cohort	P. Sax	Poster 675
Decreasing oral induction duration in support of LAI ART use with hard-to-reach populations	A. Rana	Poster 692
At home CAB/RPV provides novel approach to achieve viral suppression in adherence challenged PWH	M. Dieterich	Poster 1318
Safety and pharmacokinetics of long-acting cabotegravir and rilpivirine in children between 20-40kgs	M. Archary	Poster 1046
Interim Week 48 results in South African youth living with HIV on long-acting injectable therapy: AFINAty study	L. Jennings	Poster 679
Pre-clinical evaluation of effector function-enhanced variants of N6 bnAb	D. Wensel	Poster 547
Fostemsavir		
Temsavir treatment improves the recognition of HIV-1 infected cells by broadly neutralizing antibodies (bnAbs)	H. Qi	Poster 507
Characteristics and treatment outcomes of people with HIV prescribed fostemsavir in the trio cohort	M. Ramgopal	Poster 699
Dolutegravir		
Dolutegravir Does Not Reduce Levonorgestrel or Medroxyprogesterone Acetate Concentrations in WLWH	R. Ryan	Oral Abstract 119 10 March 2025 12:39-12:46 PT
PK and safety of chronic dolutegravir administration in neonates exposed to HIV-1 (IMPAACT 2023)	J. Momper	Poster 1047

Baseline and emergent resistance profiles in the African paediatric CHAPAS-4 trial	A. Bamford	Poster 123
Drug interactions between dolutegravir (DTG) and escalating doses of rifampicin (RIF): DORIS study	Y. Singh	Poster 645
Switching to DTG/3TC vs. BIC/FTC/TAF and steatotic liver disease: A sub-study of PASODOBLE Trial	J. Pineda	Poster 764
Depression, sleep, and anxiety among pregnant and postpartum women using dolutegravir and efavirenz	D. Wu	Poster 986
Changes in body composition in people with HIV switching to DTG/3TC or BIC/TAF/FTC	E. Martinez	Poster 897
Effectiveness and inflammatory markers after 144 weeks of switch to DTG/3TC in a randomized trial	E. Blomme	Poster 663
Switch to DTG/3TC vs BIC/FTC/TAF (PASO-DOBLE study): Efficacy and Weight Changes by Predefined Subgroups	J. Tiraboschi	Poster 661
Impact of art simplification with dolutegravir and lamivudine on the HIV reservoir	Fombellida-Lopez	Poster 664
Risk of obesity, cardiometabolic disease and MACE after switch to an integrase inhibitor in REPRIEVE	E. Kileel	Poster 838
Risk of incident hypertension with common antiretroviral agent combinations in the OPERA cohort	G. Pierone Jr	Poster 823
General HIV		
Brain volume normalization after 96 weeks of ART started during acute HIV infection	R. Paul	Oral Abstract 167 12 March 2025 10:00 AM PT
People with HIV exhibit structural brain changes following infection with SARS-Cov-2	J. Bolzenius	Oral Abstract 174 12 March 2025 10:00 AM PT
Frailty is associated with higher MACE incidence but does not appear to modify pitavastatin effects	K. Erlandson	Oral Abstract 179 12 March 2025 10:00 AM PT
Plaque, inflammation, subclinical myocardial injury and MACE in the REPRIEVE mechanistic substudy	S. Grinspoon	Oral Abstract 178 12 March 2025 10:00 AM PT
Cancer incidence in women with HIV in Europe and Australia: a combined D:A:D and RESPOND cohort analysis	W. M. Han	Poster 803
Statin effect heterogeneity on plaque volume & composition in the REPRIEVE mechanistic substudy	B. Foldyna	Poster 850
No evidence of a detrimental effect of pitavastatin on neurocognitive function among people with HIV	K. Erlandson	Poster 624
Prognostic factors of physical function decline in the PREPARE study	G. Ditzenberger	Poster 881
Time-updated win ratio aligns with primary REPRIEVE findings and suggests early pitavastatin benefit	E. Smith	Poster 853
Determinants of steatotic liver disease among people with HIV in Europe and Australia	C. Riebensahm	Poster 762
Hospitalization incidence among young children living with HIV in the Western Cape, South Africa	K. Anderson	Poster 1051
People with HIV at high cardiovascular risk were undertreated with statins	S. Esser	Poster 851

Increasing methamphetamine use and group sex observed in MSM with acute HIV infection in Bangkok	P. Chan	Poster 1144
Heart failure risk and events in people with HIV in the REPRIEVE trial	M. Watanabe	Poster 818
Cognitive trajectories 1 year before and after COVID-19 in an AHI cohort	F. Ocampo	Poster 926
Immune and virologic trajectories 1.5 years before and after COVID-19 in an early-treated HIV cohort	F. Ocampo	Poster 931
ART exposure and accelerated aging in PLHIV: insights from proteomic and methylation clocks	N. Vadaq	Poster 866
CCR5 Expression Is Critical for the Maintenance of HIV Control and Reservoir Size	J. dos Santos	Poster 563
Genetic regulation of immune responses to CMV in spontaneous HIV controllers	S. Ruijten	Poster 499
Delayed HIV-1 rebound correlates with enhanced CD8 T Cell activation in human trials	R. Thomas	Poster 484
Rapid clearance of the inducible HIV-1 reservoir after initiation of antiretroviral therapy	M. Puertas	Poster 571
Virulent HIV-1B: clinical challenges and proteomic insights	K. Mehta	Poster 358
Distinct metabolic perturbations link liver steatosis and incident CVD in lean but not obese PLHIV	N. Vadaq	Poster 760
Mitochondrial gene variants in VARS2 influence HIV reservoir and T cells in European HIV controllers	V. Rios Vazquez	Poster 487
Multiomics Clustering Reveals Distinct HIV Reservoir Profiles in the 2000HIV Cohort	V. Rios Vazquez	Poster 565
Heterogeneity of PD-1 Expression in PLHIV and Its Relationship With Host and Viral-Related Factors	A. Navas	Poster 462
Residual HIV Viremia Associates With Reservoir Size, but Not With Immune Activation or Inflammation	T. Otten	Poster 355
Neuronal injury in a subset of individuals during acute HIV infection and after immediate treatment	P. Chan	Poster 615
Early HIV-1 genetic diversity includes CTL and drug resistance mutations	J. Coffin	Poster 346
RV550: the effects of IL-15 super-agonist N-803 with ART in acute infection on T and NK cells	H. Takata	Poster 444
RV550: Safety and virological outcomes in blood and lymph nodes of N-803 with ART in acute infection	C. Sacdalan	Poster 512
Sex-based differences and genetic regulation of cytokine responses in people living with HIV	S. Ruijten	Poster 371
Females with HIV favor interferon responses over inflammation upon TLR7 activation	A. Huber	Poster 470
Translational bNAbs		
Maximizing benefits to participants in analytic treatment interruption studies with bnAb infusions	Y. Li	Poster 508
Sensitivity of HIV-1 CRF01_AE Envelopes to Broadly Neutralizing Antibodies VRC07-523 and PGDM1400	G. Smith	Poster 421

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About *Apretude* (cabotegravir LA)
Apretude is a medicine used for preventing sexually transmitted HIV-1 infection (pre-exposure prophylaxis or PrEP) in adults and adolescents weighing at least 35 kg who are at high risk of being infected. Individuals must have a negative HIV-1 test prior to initiating *Apretude* (with or without an oral lead-in with oral cabotegravir) for HIV-1 PrEP. It should be used in combination with safer sex practices, such as using condoms. *Apretude* contains the active substance cabotegravir.

Please consult the full Prescribing Information here.

About *Cabenuva* (cabotegravir + rilpivirine)
Cabenuva is indicated as a complete regimen for the treatment of HIV-1 infection in adults and adolescents 12 years and older and weighing at least 35 kg to replace the current antiretroviral regimen in those who are virologically suppressed (HIV-1 RNA <50 c/ml) on a stable antiretroviral regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.

The complete regimen combines the integrase strand transfer inhibitor (INSTI) cabotegravir, developed by ViiV Healthcare, with rilpivirine, a non-nucleoside reverse transcriptase inhibitor (NNRTI) developed by Janssen Sciences Ireland Unlimited Company. Rilpivirine tablets are approved in the US and when used with cabotegravir is indicated for short-term treatment of HIV-1 infection in adults and adolescents 12 years and older and weighing at least 35 kg who are virologically suppressed (HIV-1 RNA less than 50 copies/mL) on a stable regimen with no history of treatment failure and with no known or suspected resistance to either cabotegravir or rilpivirine.

INSTIs inhibit HIV replication by preventing the viral DNA from integrating into the genetic material of human immune cells (T-cells). This step is essential in the HIV replication cycle and is also responsible for establishing chronic disease. Rilpivirine is an NNRTI that works by interfering with an enzyme called reverse transcriptase, which stops the virus from multiplying.

Please consult the full Prescribing Information here.

About *Dovato* (dolutegravir and lamivudine)
Dovato is indicated for the treatment of Human Immunodeficiency Virus type 1 (HIV-1) infection in adults and adolescents above 12 years of age weighing at least 40 kg, with no known or suspected resistance to the integrase inhibitor class, or lamivudine.

Please consult the full Prescribing Information here.

About ViiV Healthcare
ViiV Healthcare is a global specialist HIV company established in November 2009 by GSK (LSE: GSK) and Pfizer (NYSE: PFE) dedicated to delivering advances in treatment and care for people living with HIV and for people who are at risk of acquiring HIV. Shionogi became a ViiV shareholder in October 2012. The company's aims are to take a deeper and broader interest in HIV and AIDS than any company has done before and take a new approach to deliver effective and innovative medicines for HIV treatment and prevention, as well as support communities affected by HIV. For more information on the company, its management, portfolio, pipeline, and commitment, please visit viivhealthcare.com.

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About GSK
GSK is a global biopharma company with a purpose to unite science, technology, and talent to get ahead of disease together. Find out more at gsk.com.

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Cautionary statement regarding forward-looking statements
GSK cautions investors that any forward-looking statements or projections made by GSK, including those made in this announcement, are subject to risks and uncertainties that may cause actual results to differ materially from those projected. Such factors include, but are not limited to, those described under Item 3.D "Risk factors" in GSK's Annual Report on Form 20-F for 2024.

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References

[1] Khan T, *et al.* PILLAR 12 Month Clinical Results: Zero HIV acquisition and High Persistance with CAB LA for PrEP. Presented at the Conference on Retroviruses and Opportunistic Infections (CROI 2025), 9-12 March, San Francisco, CA
[2] Grinsztejn B, *et al.* ImPrEP CAB Brasil: Enhancing PrEP coverage with CAB_LA in Young Key Populations. Presented at the Conference on Retroviruses and Opportunistic Infections (CROI 2025), 9-12 March, San Francisco, CA
[3] Sax P, *et al.* Outcomes on Cabotegravir + Rilpivirine in Suppressed People with HIV (PWH) in TRIO Health US Cohort. Presented at the Conference on Retroviruses and Opportunistic Infections (CROI 2025), 9-12 March, San Francisco, CA
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[6] Kityo C, *et al.* Randomized Trial of Cabotegravir and Rilpivirine Long-Acting in Africa (CARES): Week 96 Results. Presented at the Conference on Retroviruses and Opportunistic Infections (CROI 2025), 9-12 March, San Francisco, CA
[7] Tiraboschi JM, *et al.* Switch to DTG/3TC vs BIC/FTC/TAF (PASO-DOBLE study): Efficacy and Weight Changes by Predefined Subgroups. Presented at the Conference on Retroviruses and Opportunistic Infections (CROI 2025), 9-12 March, San Francisco, CA
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[9] Rogg L, *et al.* Proof-of-Concept Trial of VH4524184 (VH-184), a Third-Generation Integrase Strand Transfer Inhibitor. Presented at the Conference on Retroviruses and Opportunistic Infections (CROI 2025), 9-12 March, San Francisco, CA
[10] Griesel R, *et al.* Proof-of-Concept Trial of Oral VH4011499 (VH-499), a New HIV-1 Capsid Inhibitor. Presented at the Conference on Retroviruses and Opportunistic Infections (CROI 2025), 9-12 March, San Francisco, CA